Gp 1645 #5/7R
PATENT
454312-3140 10/18/99

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Briles et al.
U.S. Serial No.	:	09/298,523
Filing Date	:	April 23, 1999
For	:	PNEUMOCOCCAL SURFACE PROTEIN C (PSPC), EPITOPIC REGIONS AND STRAINS THEREOF AND USES THEREFOR

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on October 8, 1999.

Thomas J. Kowalski, Reg. No. 32,147

Name of Applicant, Assignee or Registered Representative

Thomas J. Kowalski

Signature

October 8, 1999

Date of Signature

745 Fifth Avenue
New York, NY 10151

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

The Examiner's attention is respectfully directed to the fact that this application claims priority from U.S. Provisional application Serial No. 60/082,728, and to the following documents:

1. Hammerschmidt et al., "SpsA, A Novel Pneumococcal Surface Protein With Specific Binding to Secretory Immunoglobin A and Secretory Component, Molecular Microbiology", vol. 25, pp. 1113-1124, 1997;

2. Tomasz, A., "Choline in the Cell Wall of a Bacterium: Novel Type of Polymer-Linked Choline in Pneumococcus, Science", vol. 157, pp. 694-697, 1967;

3. Briese et al., "Interactions of the Pneumococcal Amidase with Lipoteichoic Acid and Choline", Eur. J. Biochem., vol. 146, pp. 417-427, 1985;

4. Sanchez-Beato et al., "Molecular Characterization of a Family of Choline-Binding Proteins of *Clostridium beijerinckii* NCIB 8052. Evolution and Gene Redundancy in Prokaryotic Cell", Gene, vol. 180, pp. 13-21, 1996;

5. Sanchez-Beato et al., "Molecular Characterization of PcpA: A Novel Choline-Binding Protein of *Streptococcus Pneumoniae,* FEMS Microbiology Letters 164, pp. 207-214, 1997;

6. Banas et al., "Sequence Analysis of the Gene for the Glucan-Binding Protein of *Streptococcus mutans* Ingritt", Infection and Immunity, vol. 58, no. 3, pp. 667-673, 1990;

7. Briles et al., "PspA and PspC: Their Potential for Use as Pneumococcal Vaccines", Microbial Drug Resistance, vol. 3, no. 4, pp. 401-408, 1997;

8. Briles et al., "PspA, a Protection-Eliciting Pneumococcal Protein: Immunogenicity of Isolated Native PspA in Mice", Vaccine, vol. 14, no. 9, pp. 858-867, 1996;

9. McDaniel et al., "Use of Insertional Inactivation to Facilitate Studies of Biological Properties of Pneumococcal Surface Protein A (PspA), J. Exp. Med., vol. 165, pp. 381-394, February 1987;

10. McDaniel et al., "PspA, A Surface Protein of *Streptococcus pneumoniae,* Is Capable of Eliciting Protection Against Pneumococci of More Than One Capsular Type", Infection and Immunity, pp. 222-228, January 1991;

11. McDaniel et al., "Molecular Localization of Variable and Conserved Regions of pspA and Identification of Additional pspA Homologous Sequences in Streptococcus pneumoniae", Microbial Pathogenesis, pp. 261-269, 1992;

12. McDaniel et al., "Localization of Protection-Eliciting Epitopes on PspA of Streptococcus pneumoniae Between Amino Acid Residues 192 and 260", Microbial Pathogenesis, pp. 323-327, 1994;

13. McDaniel et al., "Monoclonal Antibodies Against Surface Components of *Streptococcus Pneumoniae*", Monoclonal Antibodies Against Antibodies, volume III, pp. 143-164;

14. McDaniel et al., "Immunization with a Plasmid Expressing Pneumococcal Surface Protein A (PspA) Can Elicit Protection Against Fatal Infection with Streptococcus Pneumoniae", Gene Therapy, vol. 4, pp. 375-377, 1997;

15. McDaniel et al., "Analysis of a Surface Protein of Streptococcus pneumoniae Recognized by Protective Monoclonal Antibodies", Microbial Pathogenesis, vol. 1, ppp. 519-531, 1986;

16. McDaniel et al., "Comparison of the PspA Sequence from *Streptococcus pneumoniae* EF5668 to the Previously Identified PspA Sequence from Strain Rx1 and Ability of PspA from EF5668 to Elicit Protection against Pneumococci of Different Capsular Types", Infection and Immunity, vol. 66, no. 10, pp. 4748-4754, October 1998;

17. McDaniel et al. "Use of Insertional Inactivation To Facilitate Studies of Biological Properties of Pneumococcal Surface Protein A (PspA)", J. Exp. Med., vol. 165, pp. 381-394, February 1987;

18. McDaniel et al. "Monoclonal Antibodies Against Protease-Sensitive Pneumococcal Antigens Can Protect Mice From Fatal Infection With Streptococcus Pneumoniae", J. Exp. Med., vol. 160, pp. 386-397, August 1984;

19. Devereux et al. "A Comprehensive Set of Sequence Analysis Programs for the VAX", Nucleic Acids Research, vol. 12, number 1, pp. 387-395;

20. Wu et al., "Intranasal Immunization of Mice with PspA (Pneumococcal Surface Protein A) Can Prevent Intranasal Carriage, Pulmonary Infection, and Sepsis with *Streptococcus pneumoniae*", The Journal of Infectious Diseases, pp. 839-846, 1997;

21. Yother et al., "Truncated Forms of PspA That are Secreted From *Streptococcus pneumoniae* and Their Use in Functional Studies and Cloning of the pspA Gene", Journal of Bacteriology, pp. 610-618, 1992;

22. Tart et al., "Truncated *Streptococcus pneumoniae* PspA Molecules Elicit Cross-Protective Immunity Against Pneumococcal Challenge in Mice", The Journal of Infectious Diseases, vol. 173, pp. 380-386, 1996;

23. Crain et al., "Evidence for the Simultaneous Expression of Two PspAs by a clone of capsular Serotype 6B Strepotococcus Pneumoniae", Microbial Pathogenesis, vol. 21, pp. 265-275, 1996;

24. Crain et al. "Pneumococcal Surface Protein A (PspA) Is Serologically Highly Variable and Is Expressed By All Clinically Important Capsular Serotypes of *Streptococcus pneumoniae*", Infection and Immunity, vol. 58, no. 10, pp. 3293-3299, October 1990;

25. Yamamoto et al., "Oral Immunization with PspA Elicits Protective Humoral Immunity Against *Streptococcus Pneumoniae* Infection", Infection and Immunity, vol. 65, no. 2, pp. 640-44, February 1997;

26. Yamamoto et al., "A Nontoxic Adjuvant for Mucosal Immunity to Pneumococcal Surface Protein A[1]", The Journal of Immunology, vol. 161, pp. 4115-4121, 1998;

27. Wortham et al., "Enhanced Protective Antibody Responses to PspA After Intranasal or Subcutaneous Injections of PspA Genetically Fused to Granulocyte-Macrophage Colony-Stimulating Factor or Interleukin-2", Infection and Immunity, vol. 66, no. 4, pp. 1513-1520, April 1998;

28. Nayak et al., "A Live Recombinant Avirulent Oral Salmonella Vaccine Expressing Pneumococcal Surface Protein A Induces Protective Responses Against *Streptococcus pneumoniae*", Infection and Immunity, vol. 66, no. 8, pp. 3744-3751, August 1998;

29. Yother et al., "Structural Properties and Evolutionary Relationships of PspA, a Surface Protein of *Streptococcus pneumoniae*, as Revealed by Sequence Analysis", Journal of Bacteriology, vol. 174, no. 2, pp. 601-609, January 1992;

30. Ralph et al., "Cross-Reactive Protein Eliciting Epitopes of Pneumococcal Surface Protein A", Annals of New York Academy of Sciences, pp. 361-363, undated;

31. E. AlonsoDeVelasco et al., "Streptococcus pneumoniae: Virulence Factors, Pathogenesis, and Vaccines", Microbiology Reviews, vol. 59, no. 4, pp. 591-603, December 1995;

32. Yother et al. "Pneumococcal Surface Protein A: Structural Analysis and Biological Significance", Genetics and Molecular Biology of Streptococci, Lactococci and Enterococci, American Society for Microbiology, Washington, D.C., 1991, pp. 88-91;

33. Talkington et al., "A 43-Kilodalton Pneumococcal Surface Protein PspA: Isolation, Protective Abilities, and Structural Analysis of the Amino-Terminal Sequence", Infection and Immunity, vol. 59, no. 4, pp. 1285-1289, April 1991;

34. Swiatlo et al. "Oligonucleotides Identify Conserved and Variable Regions of p*spA* and *psp*A-Like Sequences of *Streptococcus pneumoniae*", Gene, vol. 188, pp. 279-284, 1997;

35. Barrosso et al., "Nucleotide Sequence of Clostridium Difficile Toxin B Gene" Nucleic Acids Research, vol. 18, no. 13, p 4004;

36. Garcia et al., "Nucleotide Sequence and Expression of the Pneumococcal Autolysin Gene From Its Own Promoter In *Escherichia coli*", Gene, vol. 43, pp. 265-272, 1986;

37. Dove et al., "Molecular Characterization of the *Clostridium difficile* Toxin A Gene", Infection and Immunity,vol. 58, no. 2, pp. 480-488, 1990;

38. Yother et al., "Novel Surface Attachment of the Streptococcus Pneumoniae Protein PspA", Journal of Bacteriology, pp. 2976-2985, May 1994;

39. Abstract of 90th Annual Meeting of the American Society for Microbiology, p. 98, item D-106, May 1990;

40. Abstract of 89th Annual Meeting of the American Society for Microbiology, p. 125, item D-257, May 1989;

41. Abstract of ASM Conference on Streptococcal Genetics, p. 77, item 2c-21, undated;

42. Brooks-Walter, A., *et al.*, *The pspC gene encodes a second pneumococcal surface protein homologous to the gene encoding the protection-elicting PspA protein of Streptococcus pneumoniae.* ASM Anunal Meeting (Abstract), 1997; and

43. Gray, B.M., *Pneumoccal infection*, in *Bacterial Infection*, P.E. Brachman, Editor. 1997, Plenum Publishing Corporation: New York.

REMARKS

A copy of all of the foregoing documents is enclosed, together with a PTO-1449 (in duplicate) listing the foregoing documents.

The Examiner is respectfully requested to consider, and make of record, the documents cited herein.

Since this Information Disclosure Statement is being filed before the first Office Action, no fee is believed necessary or due for considering and making of record the documents cited herein. This Information Disclosure Statement is not a representation that any of the cited documents are considered pertinent, or that any of the cited documents are indeed prior art.

Please charge any fee required for consideration and making of record the documents cited herein, or credit any overpayment therein, to Deposit Account No. 50-0320.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

Date: October 8, 1999

By _____
Thomas J. Kowalski
Reg. No. 32,147
Tel. (212) 588-0800

Enclosures